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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---------------------------------|-------------|----------------------|---------------------|------------------|
| 10/086,062 | 02/28/2002 | Joseph M. Jilka | P04532US1 | 3714 |
| 22885 | 7590 | 11/28/2003 | EXAMINER | |
| MCKEE, VOORHEES & SEASE, P.L.C. | | | EPPS FORD, JANET L | |
| 801 GRAND AVENUE | | | ART UNIT | |
| SUITE 3200 | | | PAPER NUMBER | |
| DES MOINES, IA 50309-2721 | | | 1635 | |

DATE MAILED: 11/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|---------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/086,062 | JILKA ET AL. | |
| | Examiner | Art Unit | |
| | Janet L. Epps-Ford, Ph.D. | 1635 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 7-40 is/are rejected.
- 7) ☒ Claim(s) 6 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5, 7</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The Sequence listing in computer readable form received 2-28-02 is technically sound and has been entered into the pending nucleic acid STIC database of the USPTO.

Priority

2. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number. In the instant case, Applicants have not included an amendment to the first line of the specification, which indicates that the instant application is a continuation of US Serial No. 09/590,558, filed 6/09/2000, now abandoned.

Claim Objections

3. Claims 3-4, 6, 11, 21-22, 26, and 30 are objected to for failing to recite the appropriate sequence identifiers. According to 37 CFR 1.821 through 1.825, Applicants are required to assign a sequence identifier (SEQ ID NO) for every disclosed unbranched nucleic acid sequence of 10 or more nucleotides and list these sequences individually in a Sequence Listing as a separate part of the disclosure.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 4, 7-9, 10-12, and 20-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 recites the limitation “said heat shock sequence” in claim 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 7 recites the limitation “the heat shock element region” in claim 1. There is insufficient antecedent basis for this limitation in the claim.

Claims 8 and 27 recite the limitation “the overlapping HSE”. There is insufficient antecedent basis for this limitation in these claims. Additionally, claims 8 and 27 recite “wherein said sequence includes a deletion of the overlapping HSE at position –204-190.” This statement is vague and indefinite since Applicants do not indicate which specific nucleic acid sequence the position –204 - -190 refers to.

Claim 9 recites “[t]he promoter sequence of claim 1 further comprising a DNA binding factor or transcription factor.” This phrase is vague and indefinite since DNA binding factors and transcription factors are known in the art to be proteins that bind to specific sequences within a nucleic acid molecule, they are not known to be nucleic acid sequences. Therefore, it is unclear how the nucleic acid promoter of claim 1 is to comprise a DNA binding factor or a transcription factor.

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Claims 10-12 recites the limitation “wherein said transcription factor” in claim 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 11-12 recites “said PSI element” in claim 10. There is insufficient antecedent basis for this limitation in the claim.

Claims 20-31 recite “[T]he promoter sequence of claim 19,” this phrase is unclear because claim 19 recites a “[A] method for causing expression of a structural gene.” It appears that dependent claims 20-31 are drawn to product claims and not to a method as recited in independent claim 19. It is likely that Applicants intended claim 20, for example, to recite: “[T]he method of claim 19, wherein the promoter sequence includes a single heat shock element.”

Claims 23-26 recite the limitation “said sequence comprises two adjacent heat shock elements,” in claim 20. There is insufficient antecedent basis for this limitation in claim 20, since claim 20 recites that the sequence includes a single heat shock element.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(c) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

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7. Claims 1-5, 13-22, 32-35, and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Quail et al. (EP0342926 A2: EP) or under 35 USC 102(e) as being anticipated by Quail et al. (US Patent 6,054,574:US)

The instant claims read on a promoter sequence capable of directing expression of a nucleotide sequence in a plant cell, said sequence comprising: a ubiquitin promoter sequence, wherein said sequence includes a modification so that it does not include two overlapping heat shock elements. Claims 32-35 recite wherein the promoter sequence of claim 1 is capable of driving expression to specific regions of a plant including to the leaf, root, seed and endosperm. Since claims 32-35 recite product claims, absent evidence to the contrary, if the prior art discloses the claimed product, the prior art product would be expected to have the same properties as applicant's compounds. Additionally, the vector constructs comprising the ubiquitin promoters disclosed in the prior art, absent evidence to the contrary, would be expected to have the same properties as Applicant's vector constructs.

Quail et al. disclose a DNA fragment comprising a plant ubiquitin promoter region, wherein said promoter comprises at least one heat shock element (EP col. 23, lines 40-45; US col. 20, lines 21-25). The heat shock elements of Quail et al. comprise the following sequences: 5'-CTGGACCCCTCTCGA-3', and 5'-CTCGAGAGTTCCGCT-3' (EP col. 21, lines 55-60;US: col. 19, lines 1-3). Additionally, Quail et al. teach that an individual heat shock sequence may be arbitrarily positioned at different loci within the ubiquitin promoter and that it may be chemically altered in sequence or be replaced with a synthetic homologous sequence, so long as the modified promoter sequence retains ubiquitin promoter function, which comprises the initiation, direction and regulation of transcription under stress and non-stress conditions. Moreover, Quail

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et al. teach that the biochemical techniques required to insert and/or delete nucleotides and to manipulate the resultant DNA fragments are well known to those skilled in the art of genetic redesigning (EP: col. 22, lines 21-33; US: col. 19, lines 28-39).

Quail et al. teach each and every aspect of the instant invention thereby anticipating Applicant's claimed invention.

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

9. Claims 1, 7-8, 13-19, 27, 32-38, and 40 are rejected under 35 U.S.C. 102(a) as being anticipated by Goldsbrough et al. (WO00/15810 A1).

The Goldsbrough et al. reference describes the construction of plant expression constructs (pPBI97-2BdUN1 & pPBI92-2BdUN1), and methods of using these constructs for the expression of genes in plant tissues. The constructs comprise a reconstituted ubiquitin regulatory system comprising a modified ubiquitin promoter that lacks the two overlapping heatshock consensus sequence elements (page 32, 2nd paragraph).

It is noted that claims 8 and 27 recite the deletion of the overlapping HSE at position -204- -190, although it is unclear which sequence applicants are referring to, these claims are interpreted as being drawn to a promoter wherein the overlapping heat shock elements are deleted.

Claim 36 recites a promoter sequence capable of directing expression of a nucleotide sequence in a plant cell comprising: a modification that increases the endosperm/embryo

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expression of a protein when compared to the ratio from a wild-type ubiquitin promoter. According to the specification as filed a ubiquitin promoter comprising a deletion of one or both of the heat shock elements would increase the endosperm/embryo expression of a nucleotide sequence regulated by the modified ubiquitin promoter (see page 30, and page 52, table 4). As described above Goldsbrough discloses vector constructs comprising a modified ubiquitin promoter comprising a deletion of both heat shock elements, therefore the constructs of Goldsbrough et al. would anticipated Applicant's claimed invention.

Goldsbrough et al. teach each and every aspect of the instant invention thereby anticipating Applicant's claimed invention.

Conclusion

10. Claim 6 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

11. Claim 26 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

12. Claims 6 and 26 are free of the prior art. Quail et al. and Goldsbrough et al. teach modified ubiquitin promoters, wherein said promoter comprises at least one heat shock element, or wherein the heat shock elements are deleted from said ubiquitin promoter. However, neither reference discloses a modified ubiquitin promoter comprises the following sequence: 5'-CTGGAC CCCTCTCGACTCGAG AGTTCCGCT-3'.

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Specification

13. The attempt to incorporate subject matter into this application by reference to WO 98/39641, published September 11, 1998, on page 6, 3rd paragraph, is improper because this publication does not disclose the preferential expression in seed by the use of the Ubi-1 promoter as indicated by Applicants. The WO 98/39641 publication relates to a method for the inspection of a part by thermal imaging, and not to the use of ubiquitin promoters.

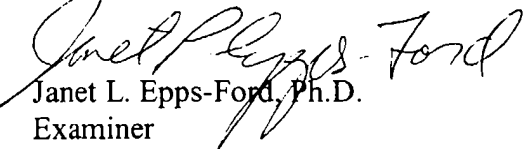
Notice of References Cited

14. All references included on the attached Notice of References Cited have been previously forwarded to Applicants during the prosecution of parent application 09/590,588 or are included in Applicant's Information Disclosure Statement.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford, Ph.D. whose telephone number is 703-308-8883. The examiner can normally be reached on Monday-Thursday, 8:30 AM - 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 703-308-0447. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Janet L. Epps-Ford, Ph.D.
Examiner
Art Unit 1635

JLE